

Notice of Allowability

Application No.

10/511,458

Applicant(s)

INOSE, KEN

Examiner

Art Unit

Amanda M. Shaw

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Request for Continued Examination filed 12/27/2006.
2. ☒ The allowed claim(s) is/are 1-4.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>9/25/2006</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |

9. ☐ Other _____


RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given by telephone on February 15, 2007 by Che Chereskin.

2. The information disclosure statement (IDS) submitted on 9/25/2006 has been considered. The reference has been considered but has a line drawn through it because there is no publication date for the reference.

3. The application has been amended as follows:

In the Claims:

Claim 1 has been rewritten as follows:

1. A method for detecting a target nucleic acid having a target sequence in a sample, comprising the steps of:

(a) obtaining a first probe comprising a nucleic acid which has a specific region having a sequence complementary to the target sequence and a nonspecific region having a sequence that is not complementary to the target sequence of the target nucleic acid; and a second probe comprising a nucleic acid which has a first region that

is complementary to at least a portion of the nonspecific region of the first probe, a loop region that does not have a sequence complementary to the first probe, and a second region that is complementary to at least a portion of the specific region of the first probe, wherein the nucleic acid of the second probe is labeled with a labeling material generating a signal by which formation of a loop can be detected;

(b) mixing the first probe and the second probe, thereby forming a mixture wherein the loop in the loop region of the second probe is formed when the second probe is annealed with the first probe, thereby quenching the signal from the labeling material in the absence of a target nucleic acid;

(c) adding the sample to the mixture of step (b), whereby the target nucleic acid in the sample anneals with the first probe, thereby releasing the second probe; and

(d) detecting an increase in the signal of the labeling material in the presence of the target nucleic acid compared to the signal obtained in step (b), thereby detecting the target nucleic acid, wherein the signal is quenched when the first probe and the second probe are annealed and not quenched when the first probe and the second probe are not annealed.

Claim 4 has been rewritten as follows:

4. The method according to claim 1, wherein the detection of the increase in the signal is performed quantitatively, thereby quantifying the target nucleic acid.

Claim 5 has been cancelled.

**THE FOLLOWING IS AN EXAMINER'S STATEMENT OF REASONS FOR
ALLOWANCE:**

4. While the prior art of Weston et al (US Patent 6391593 Issued 5/2002) does teach a method for detecting a nucleic acid sequence using two hybridization probes it does not teach or suggest using two hybridization probes where in the absence of a target nucleic acid the two probes hybridize to each other, and the second probe forms a loop region that quenches a labeling material present on the second probe. When a sample is added to the reaction where the first and second probes are hybridized, the first probe hybridizes to the target nucleic acid thereby releasing the second probe which causes the loop region of the second probe to open up and no longer quench the labeling material present on the second probe. This results in an increase in the fluorescent signal compared to when no target nucleic acid is present.

Conclusion

5. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571)

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272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Examiner
Art Unit 1634



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